UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

SERIAL NUMBER	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/466,340	06/06/95	LI	Y 325300-449

EXAMINER	
DAGUAM P	
ART UNIT	**PAPER NUMBER**
1812	14

DATE MAILED: 02/10/97

18N2/0210

ELLIOT M OLSTEIN
CARELLA BYRNE BAIN GILFILLAN CECCHI
STEWART & OLSTEIN
6 BECKER FARM ROAD
ROSELAND NJ 07068

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

☐ This application has been examined ☑ Responsive to communication filed on Oct 29, 1996 ☐ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), ~~day~~ from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. ☑ Notice of References Cited by Examiner, PTO-892.
2. ☑ Notice of Draftsman's Patent Drawing Review, PTO-948.
3. ☑ Notice of Art Cited by Applicant, PTO-1449.
4. ☐ Notice of Informal Patent Application, PTO-152.
5. ☐ Information on How to Effect Drawing Changes, PTO-1474..
6. ☐ _____.

Part II SUMMARY OF ACTION

1. ☑ Claims 21-54 are pending in the application.

   Of the above, claims _____ are withdrawn from consideration.

2. ☐ Claims _____ have been cancelled.
3. ☐ Claims _____ are allowed.
4. ☑ Claims 21-54 are rejected.
5. ☐ Claims _____ are objected to.
6. ☐ Claims _____ are subject to restriction or election requirement.
7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice of Draftsman's Patent Drawing Review, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____. has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed _____, has been ☐ approved; ☐ disapproved (see explanation).
12. ☐ Acknowledgement is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. _____ ; filed on _____.
13. ☐ Since this application apppears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

EXAMINER'S ACTION

DETAILED ACTION

1. The preliminary amendments filed 9/22/95, 10/29/96, 12/12/96 and 12/27/96 and the amendment filed 11/25/96 have been entered.

2. The preliminary amendment filed 10/29/96 is objected to for the following reason: In claim 21, the unattached phrase "a polypeptide comprising amino acid 2 to 352 of SEQ ID NO: 2" is extraneous material within the section In the Claims. Appropriate corrections required.

3. The amendment filed 9/22/95 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: Addition of ATCC deposit No:97183 is new matter because Applicant has not indicated that this deposit is the same as a material specifically identified in the application as filed. The specification made reference only to the genus of cDNAs encoding the HDGNR10 polypeptide having an amino acid sequence as set forth in SEQ ID NO:2.

Applicant is required to cancel the new matter in the response to this Office action.

4. Applicant's election of Group I, claims 1-6, with traverse in Paper No. 11 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

5. The disclosure is objected to because of the following informalities: In claims 23 and 24 the word "polypeptide" is misspelled.

Appropriate correction is required.

6. Claims 24 and 27 are identical in scope and content and are therefore objected to as being duplicate claims. One of the duplicate claims should be canceled or otherwise amended to delimit a different scope of the invention. See 37 C.F.R. § 1.75(b); applicant's attention is also directed to M.P.E.P. § 706.03(k).

7. The numbering of claims is not accordance with 37 CFR 1.126. The original numbering of the claims must be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When claims are added, except when presented in accordance with 37 CFR 1.121(b), they must be renumbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

Misnumbered claims 38-51 have been renumbered 39-54.

Claim Rejections - 35 USC § 112

8. The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8a. Claims 45-54 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

In accordance with MPEP § 2402, if a deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by Applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the deposit has been made under the terms of the Budapest Treaty and that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent, would satisfy the deposit requirements. See 37 C.F.R. § 1.808.

If a deposit is not made under the terms of the Budapest Treaty, then the requirements may be satisfied by an affidavit or declaration by Applicants or someone associated with the patent owner who is in a position to make such assurances, or by a statement by an attorney of record over his or her signature, stating that the following criteria have been met:

(a) during the pendency of the application, access to the deposit will be afforded to one determined by the Commissioner to be entitled thereto;

(b) all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of the patent;

(c) the deposit will be maintained for a term of at least thirty (30) years and at least five (5) years after the most recent request for the furnishing of a sample of the deposited material;

(d) a viability statement in accordance with the provisions of 37 C.F.R. § 1.807 is provided; and

(e) the deposit will be replaced should it become necessary due to inviability, contamination or loss of capability to function in the manner described in the specification.

In addition, the identifying information set forth in 37 C.F.R. § 1.809(d) should be added to the specification. See C.F.R. §§ 1.803-1.809 for additional explanation of these requirements.

On page 6, lines 28-33, the specification discloses that isolated nucleic acid for the mature G-protein chemokine receptor (GDGNR10) polypeptide encoded by the cDNA of a clone deposited as ATCC Deposit No 97183, on June 1, 1995. While descriptions are given for a number of vectors (page 14, lines 4-15) and host cells (page 14, lines 10-27) suitable for use with the invention, including examples of a sub-clone derived from the deposited material (page 35-36, **Example 1**), the specification fails to provide any detail as to the identification of the particular vector used, what specific host cell contains the DNA, how the cDNA fragment was inserted into the vector or any other specific information that would allow one skilled in the art to make the deposited material described in the specification or the claims. As the specification fails to provide the necessary details to readily obtain the materials required to reproduce the instant deposited clone, no repeatable method is apparent, therefore, the deposited clone could not be made by a skilled artisan without undue experimentation.

8b. Claims 21, 22, 25, 28, 30-32, 34-36, 38, 39, 45-50, 52 and 53 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for polynucleotides encoding an amino acid sequence as set forth in SEQ ID NO: 2, does not reasonably provide enablement for polynucleotides encoding a "mature"polypeptide. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

At page 7 of the specification the applicant's describe the invention by disclosing deduced amino acid sequences of the putative "mature" polypeptide for GDGNR10 (lines 6-16). Some structural detail is given for the cDNAs in figure 1 identifying an open reading frame upon which the deduced amino acid sequences is based (page 6 lines 19-24), however, no distinction is made between a contrasting polypeptide and the "mature" polypeptide. Typically, a nascent polypeptide in a pre- or pro - form differs from a "mature" protein in that the latter lacks some structural feature which distinguishes it from the nascent molecule. Furthermore, polypeptides which are post-translationally modified are also different from their corresponding nascent polypeptide in some demonstrable way. In the case of the instant application, no such distinction based on structure, function or sequence is apparent, as the modifier "mature" imparts no unique structural or functional feature to the polypeptide of the instant application, therefore, undue experimentation would be afforded on the skilled artisan to make the molecule because the specification provides no guidance as to how a "mature" polypeptide would be discerned.

8c. Claims 38 and 39 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for producing recombinant polypeptides as set forth in SEQ ID NO: 2, does not reasonably provide enablement for all of the recombinant polypeptides produced by expression from a polynucleotide that is 95% identical to a polynucleotide that encodes a structurally undefined receptor. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

The claims as written only require that a recombinantly produced polypeptide be encoded by a polynucleotide that is at least 95% identical to all possible nucleic acid combinations that encode a structurally undefined receptor. As the abbreviation GDGNR10 does not inherently represent any particular nucleic acid sequence, there is no limitation that the resulting encoded polypeptide have any particular amino acid sequence (e.g., insertional variants leading to frame shifts such that the resulting amino acid sequence has 0% amino acid sequence identity), the claims embrace polypeptides which are neither structurally or functionally related to the disclosed cytokine receptor. Since it is well known in the art that specific amino acids are essential for proper protein folding, the random substitution of amino acid residues cannot be made indiscriminately given the potential negative effects caused by perturbations in amino acid sequence. In the absence of structural information peculiar to the instant cytokine receptor, a person of ordinary skill in the art would be unable to make a functional polypeptide encoded by a polynucleotide that is at least 95% identical to those polynucleotides encoding GDGNR10 as set

forth in SEQ ID NO: 2 without undue experimentation because selection of mutable sites in the nucleic acid sequence based on the specification would be arbitrary, a practice that does not readily lend itself to predictable outcomes commensurate with the recombinant production of functional variants of the receptor embraced by the claims.

8d. Claims 21, 22, 25, 28, 30-32, 34-36, 38 and 40 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for polynucleotides encoding an amino acid sequence as set forth in SEQ ID NO: 2, does not reasonably provide enablement for all of the polynucleotides that are 95% identical to a polynucleotide encoding a structurally undefined polypeptide. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

The specification defines GDGNR10 in functional terms as a G-protein cytokine receptor (at page 1, line 21) and uses the terms interchangeably throughout the specification. The receptor of the claims is identified by abbreviation only (GDGNR10), i.e., without reference to structural characteristics disclosed in the specification (e.g., SEQ ID NO:1) that are peculiar to GDGNR10. As the abbreviation GDGNR10 does not inherently represent any particular nucleic acid sequence, the limitation that a polynucleotide be 95% identical is meaningless in the absence of an appropriate reference molecule (e.g., SEQ ID NO: 1 and/or 2). Nucleic acid claims that lack the recitation of structural properties encompass subject matter which is not supported by the specification, such as molecules that share assigned provisional nomenclature based on the

description of general functional characteristics (e.g., G-protein chemokine receptor from human) while sharing little to no sequence identity (e.g., IL-8 type B receptor). Molecules, such as those mentioned above, that are embraced by the claims are not adequately described by the specification and could not be made or used using the guidance of the instant specification because the specification provides no guidance for how to make them or use them nor are examples provided as to how these molecules would be identified commensurate with the breadth of the claims. For example, without a sequence reference, the skilled artisan is forced to make arbitrary changes in the structure of the GDGNR10 receptor; a practice that does not lend itself to predictable functional outcomes. In the absence of an appropriate structural disclosure a person of ordinary skill in the art would be unable to make and use the molecules embraced by the claims without undue experimentation. .

8e. Claims 45-54 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

At page 6, lines 28-33, the specification discloses that isolated nucleic acid for the mature G-protein chemokine receptor polypeptide encoded by the cDNA of a clone was deposited as ATCC Deposit No 97183, on June 1, 1995. However, at the time the application was filed no deposit number was disclosed and suggests that the clone containing the cDNA encoding the instant polypeptide had not yet been deposited and/or had not yet been obtained.

9. Claims 21-50 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 21-50 are vague and ambiguous because by using the phrase "mature polypeptide" it is not clear whether this means a polypeptide that has been post-translationally modified (e.g., +glycosylated) or a peptide that has had a signal sequence removed nor is the phrase "mature" defined in the specification. Claim 26 is vague and ambiguous because a polypeptide cannot be DNA. Claims 29, 36-38 are vague and ambiguous because "polynucleotide" has an improper antecedent basis.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 21, 22, 25, 28, 30, 31, 34, 35, 38 and 40 are rejected under 35 U.S.C. 102(b) as being anticipated by Chuntharapai et al (R).

Chuntharapai et al teach a polynucleotide encoding a human chemokine receptor that is G-protein linked (i.e., IL8 type-B receptor, column 1, paragraph 5, lines 45-63) including DNA (SEQ ID NO:2), RNA (column 9, paragraph 1, lines 17-19), method of making a recombinant

vector comprising the polynucleotide (column 11, paragraph 4, lines 33-48), recombinant host cells comprising the polynucleotide (column 16, paragraph 4, lines 21-36) and a method of producing a polypeptide via expression from recombinant cells (column 18, paragraph 2 and 3, lines 25-57).

Chuntharapai et al teach all of the essential material compositions of claims 21, 22, 25, 28, 30, 31, 34, 35, 38 and 40 because the instant specification uses the abbreviation "HDGNR10" and "G-protein chemokine receptor" interchangeably and as the instant claims depend solely on the abbreviation as a point of reference and to define the polynucleotide, the claims embrace all G-protein chemokine receptors.

11. Claims 24 or 27, 29, 33, 37 and 39 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112 set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

12. As allowable subject matter has been indicated, applicant's response must either comply with all formal requirements or specifically traverse each requirement not complied with. See 37 CFR 1.111(b) and MPEP § 707.07(a).

13. Claims 23, 24, 26, 27, 29, 32, 33, 36, 37, 39 and 41-54 are free of the prior art.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daryl A. Basham, Ph.D. whose telephone number is (703) 305-2150.

If attempts to reach the examiner by telephone are unsuccessful, the examiners supervisor, Stephen Walsh, Ph.D., can be reached on (703) 308-2957. The fax phone number for this group is (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

dab
January 29, 1997

DAVID L. FITZGERALD
PRIMARY EXAMINER
GROUP 1800